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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,665	01/31/2002	Christine Leib-Mosch	10737-006001	2339

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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/914,665	LEIB-MOSCH ET AL.	
	Examin r	Art Unit	
	Shin-Lin Chen	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *12 November 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *None*.

Claim(s) objected to: *None*.

Claim(s) rejected: *1-6,8-12,20 and 21*.

Claim(s) withdrawn from consideration: *13-19*.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

S Chen

SHIN-LIN CHEN
PRIMARY EXAMINER

Shin-Lin Chen
Primary Examiner
Art Unit: 1632

Continuation of 5. does NOT place the application in condition for allowance because: Applicants cite page 17, line 23 through page 18, line 23 of the specification and Figures 2a-10b, and argue that the specification provides in vitro use of the claimed retroviral vector and should be enabled (supplemental reply, p. 6-7). This is not found persuasive because of the reasons of record. The claimed retroviral vector is considered to require an in vivo use because of the specification states "The present invention relates to retroviral expression vectors bearing promoters which may be cell-specifically controlled. The vectors are useful for example for the cell-specific expression of genes of therapeutic value in the context of a gene therapy" (specification, page 1). The in vivo use of the claimed vector is not enalbed fo the reasons of record. Further, the claims encompass using various promoter regions of different HERVs in a retroviral vector for cell-specific expression of desired genes. Sjottem et al., 1996 (Journal of Virology, Vol. 70, No. 1, p. 188-198) discloses that there are about 1,000 full-length elements and a similar number of solitary LTRs in HERV-H family of endogenous retrovirus-like elements and only a subset of HERV-H LTRs display promoter activity in human cell lines. It should be noted that this is not a new groupd for the rejection. This reference has been cited in the Official action mailed 8-27-03 (Paper No. 14). The specification indicates that "[T]he HERV-K LTR from placenta is particularly active in Hela cells, In all other cell lines, this LTR exhibits only a very weak activity... The HERV-T-S71A and HERV-E LTRs were active in none of the cell lines tested. Also, no activity at all of a HERV LTR could be observed up to now in CML cells" (specificatiln, p. 18, line 8-17). The claims encompass the use of thousands of different HERV LTR sequences. It appears that those HERV LTR sequence differ in their promoter activities dramatically from each other and their promoter activities also depend on the cell types in which they are used. Therefore, one skilled in the art at the time of the invention would not know how to use the full scope of the cliamed retroviral vector having various HERV LTR sequence for in vivo gene expression or even for in vitro gene expression to produce recombinant protein. Thus, even if only the in vitro use of the claimed vector is considered, the present invention is not enabled for the full scope of the retroviral vector claimed. In addition, page 17, line 23 through page 18, line 23 of the specification and Figures 2a 10b are all directed to the use of the vector comprising HERV LTR and nucleotide sequence encoding either reporter protein or GFP for studying the promoter activity of different HERV LTR sequences. Such in vitro use of the claimed retroviral vector would lack specific and substantial utility. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved is not considered substantial utility (see Utility Guidelines). Thus, when considering the in vitro use of the claimed retroviral vector as suggested by the applicants, the claimed retroviral vector lack speicifc and substantial utility and full scope of the claimed retroviral vector is not enabled.